



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/997,588

11/29/2001

Chen Xing Su

10209.353

6233

21999 7590 01/30/2009

KIRTON AND MCCONKIE
60 EAST SOUTH TEMPLE,
SUITE 1800
SALT LAKE CITY, UT 84111

EXAMINER

LEITH, PATRICIA A

ART UNIT

PAPER NUMBER

1655

MAIL DATE

DELIVERY MODE

01/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/997,588	Applicant(s) SU ET AL.	
	Examiner Patricia Leith	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-28 is/are pending in the application.
- 4a) Of the above claim(s) 13-23 and 27-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-12 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1 and 5-28 are pending in the application.

Claims 13-23 and 27-28 were withdrawn on the merits as they are directed toward a non-elected invention.

Claims 1, 5-12 and 24-26 were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-12 and 24-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

Art Unit: 1655

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 newly recites the limitations 'allowing fruit to ripen for 1-14 days,' 'holding the fruit in said containers for 1-30 days' and 'screen filter size between 200 and 500 microns.'

The limitation 'allowing fruit to ripen for 1-14 days' does not find support in the original specification as filed. The Instant specification teaches 'allowing fruit to ripen for 0-14 days,' however, does not teach 'allowing fruit to ripen for 1-14 days.' Applicants therefore did not teach the newly recited limitation of 1-14 days, nor did Applicants stress the importance of this now-recited narrow range. The newly recited range end-point of '1' day is new matter because the original range of '0-14 days' is a period of time comprising days, hours and seconds. There are a tremendous amount of time periods between '0-14' days as originally disclosed, and no one time period such as 1 day was originally disclosed by Applicants as being a recognized part of their invention. For example, although the original range stated '0-14 days', there is no disclosure of distinct increments of 1 day, 2 days, 3 days and so-forth. '0-14 days' includes for example, 2 min., 10 min., 15 hours, 72 hours, 81 hours and so forth. To pick and chose one point within this range after this case has been filed is considered New matter seeing that Applicants did not specifically disclose wherein the fruit was allowed to ripen for one day, or expound on the significance of a time frame of one day ripening.

The limitation 'holding the fruit in said containers for 1-30 days' does not find support in the original specification as filed. The Instant specification teaches 'holding the fruit in said containers for 1-30 days,' however, does not teach 'holding the fruit in said containers for 1-30 days.' Applicants therefore did not teach the newly recited limitation of 1-30 days, nor did Applicants stress the importance of this newly-recited more narrow range of days. Again, as stated above, there are a myriad of time 'slots' between '0-30 days' as originally claimed. Although '0-30' days may mean 0 days, 1 day, 2 days.... it may also mean 1 hour, 15 hours, 77 hours, 300 hours 21 minutes and 7 seconds and so forth. Applicants did not disclose that 1 day (24 hours) (the new end-point of the range) was of any importance nor did Applicants tend to contemplate this as their invention at the time the invention was made hence rendering this new recitation of holding the fruit in said containers for 1-30 days' New Matter.

The new limitation 'screen filter size between 200 and 500 microns' is also considered New matter. While the disclosure as filed teaches '1-2000 microns' and 'more preferably less than 500 microns,' there is no disclosure of 200-500 microns or any disclosure at all regarding a 200 micron filter size. Applicants again are choosing a specific point within a broad range which was not disclosed, and of which the importance thereof was not explicitly nor implicitly described in the original disclosure.

Art Unit: 1655

Purdue Pharma L.P. v. Faulding Inc., 230 F. 3d 1320, 1326, 56 USPQ2d 1481, 1486 (Fed. Cir. 2000). The court noted that with respect to *In re Rushig* 379 F. 2d 990, 154 USPQ 118 (CCPA 1967) that “Ruschig makes clear that one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say “here is my invention”. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure.”

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Solomon (1998).

Solomon (1998) taught many traditional and modern medicinal uses of noni. In describing the fruit of the noni tree, Solomon explained:

This ‘queen,’ scientifically known as *Morinda citrifolia* L., or noni, is a small, blossoming shrub with rounded branches and dark, glossy evergreen leaves that measure approximately a foot in length. Groupings of small, white flowers sprout at different times and eventually evolve into bumpy, egg-shaped fruit that are a few inches long and etched with many circular indentations or

Art Unit: 1655

pits (many people think noni fruit resembles a small potato. The waxy yellowish-white skin of the fruit becomes thin and translucent when the fruit is ripe, and the tasteless, whitish pulp deteriorates into a very smelly (a 'rotten cheese smell' is a common description of the odor of ripe noni), terrible-tasting semi-liquid that readily seeps through the skin of the fruit. (p. 17)

Solomon's suggested formulation for taking noni medicinally consisted of admixing 89% pure noni juice with 11% blueberry and 11% grape juice as well as other fruit juices which allowed for "a pleasant taste and smell." (see p. 92). This juice-fortified formulation of noni was prescribed by Solomon to be taken; for example in a dosage of 2 ounces before breakfast (on an empty stomach) and dinner by an adult, or one ounce before breakfast and dinner by a child (under 16 years) (see pp. 92-93 including Table 8).

It is deemed that the fruit juice of noni would necessarily contain pulp, even if it is in trace amounts. Additionally, although Solomon did not explicitly teach that the noni juice product inhibited lipid peroxidation, the only step in this method is administration of noni juice in combination with blueberry and grape juice and natural flavoring (noni juice naturally contains its own endogenous flavoring components). Hence, since the method of Solomon is the same as that of the claimed invention, and the juice is the same, the noni juice composition of Solomon must have also carried out inhibition of lipid peroxidation even though the reference is silent to this fact.

Where claim 12 requires that the liquid composition includes reconstituted *Morinda citrifolia* puree fruit juice does not distinguish from the juice as disclosed by

Art Unit: 1655

Solomon. What is *Morinda citrifolia* puree fruit juice which has been reconstituted, but the juice of *Morinda citrifolia*? No difference can be made between the MC juice of claim 12 and the MC juice of Solomon.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-12 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirazumi (1998) in view of Solomon (1998) in view of Ashurst (1999) in view of Elliot (US 1,885,401) and further in view of Beaven (GB 2215173A) and Astrauskas et al. (US 3,953,582).

Hirazumi (1998) in her dissertation, discloses the deep traditional roots noni has in the Hawaiian society; all parts of the noni plant were consumed for medicinal effects

Art Unit: 1655

(see pp. 1-5). Hirazumi taught that Peerzada et al. (1990) reported that "...the fruits were a good source of potassium and vitamin C." (see p. 7) Vitamin C is a well-known anti-oxidant vitamin. Hirazumi expounds on the prior discoveries of noni's alleged healing powers and performs detailed analysis of the anti-tumor activities of noni juice. Hirazumi prepared her starting noni juice by a traditional method:

"Yellowish-ripe fruits were collected...[and]...allowed to ripen to a soft consistency and then rinsed in... a food sanitizer. The sanitized fruits were placed in a sterile covered glass jar out in the sunlight for 1-3 days to allow the juice to seep out. Filtration or centrifugation removed the insoluble products from the juice and flash evaporation concentrated the juice." (see p. 21).

Hirazumi did not teach wherein the fruit is allowed to ripen for 1-14 days, wherein the fruit is placed into plastic lined containers and held for 1 to 30 days, mechanical separation of the seeds, peel, pulp and juice, and filtering via a centrifuge decanter with a screen filter size between 200 and 500 microns at a pressure between .1 psig and 1000 psig (it is noted that a centrifuge decanter is also known as a 'centrifugal' or a centrifuge filter or a centrifuge filtration device (*inter alia*)) or wherein the noni juice was combined with processed MC pulp, blueberry juice concentrate or grape juice concentrate. However, it is noted that the juice of Hirazumi necessarily contained 'natural flavorings' of the noni juice and hence, the teachings of Hirazumi fulfill the limitation of part (v) of claim 1.

Art Unit: 1655

Solomon (1998) taught many traditional and modern medicinal uses of noni. In describing the fruit of the noni tree, Solomon explained:

This 'queen,' scientifically known as *Morinda citrifolia* L., or noni, is a small, blossoming shrub with rounded branches and dark, glossy evergreen leaves that measure approximately a foot in length. Groupings of small, white flowers sprout at different times and eventually evolve into bumpy, egg-shaped fruit that are a few inches long and etched with many circular indentations or pits (many people think noni fruit resembles a small potato. The waxy yellowish-white skin of the fruit becomes thin and translucent when the fruit is ripe, and the tasteless, whitish pulp deteriorates into a very smelly (a 'rotten cheese smell' is a common description of the odor of ripe noni), terrible-tasting semi-liquid that readily seeps through the skin of the fruit. (p. 17)

Solomon's suggested formulation for taking noni medicinally consisted of admixing 89% pure noni juice with 11% blueberry and 11% grape juice as well as other fruit juices which allowed for "a pleasant taste and smell." (see p. 92). This juice-fortified formulation of noni was prescribed by Solomon to be taken; for example in a dosage of 2 ounces before breakfast and dinner by an adult, or one ounce before breakfast and dinner by a child (under 16 years) (see pp. 92-93 including Table 8).

Elliot (US 1,885,401) discloses a conventional method for preparing fruit juices comprising mechanically separating the rind (skin/peel), seeds and pulp from the fruit, and clarification via centrifuge filtration (see, e.g., columns 1 and 2). Elliot taught that a filter of 80 mesh was suitable for separation of the pulp from the juice (see column 2).
80 mesh = 177 microns.

Art Unit: 1655

Additionally, Ashurst (1999) taught that a 500 micron mesh (0.5 mm) is suitable for juice filtration (see p. 80, 3.3.4).

The use of plastic containers to store or place fruit in were well-known at the time the invention was made. Beaven (GB 2215173A) for example, disclosed a transparent, ventilated portable plastic container for carrying and ripening of fruits or vegetables (see entire reference, especially Abstract and figure 2).

Astrauskas et al. (US 3,953,582) disclosed that centrifuges using 150 psi pressure were known in the art for separation of solids from liquids:

The utility and hence the commercial applicability of the continuous process of Kawakami et al. is limited by the difficulty involved in the recovery of the basic alkali metal azide (the double salt) from the liquid ammonia carrier. Typically, solids suspended in liquids can be recovered by continuous centrifuging. However, centrifuges capable of operation at pressures in excess of about 150 psi are unknown. Pressure leaf filters can be employed but equipment costs and operating costs are high and such a system is not continuous. Kawakami et al. note that filtration methods are far from satisfactory. Evaporation of the ammonia to recover the double salt can likewise involve the erection of costly equipment and operation is expensive. (col. 1, lines 40-54)

Therefore, a known method for obtaining the juice from the fruit of the noni plant was to allow the fruit, which was known to be several inches long according to Solomon (within the claimed length of between one and 12 inches in diameter, when

Art Unit: 1655

the fruit is split length-wise), to ripen, placing the ripened fruit in a glass container for 1-3 days and then to process the juice from the fruit via filtration and centrifugation.

One of ordinary skill in the art would have been motivated to place MCJ in plastic lined containers in order to store the fruit prior to processing. This is considered an obvious step in that the ordinary artisan would have recognized that fruit is typically picked and placed in baskets or other types of vessels to transport to the place of processing. The choice of plastic lined containers would have been advantageous in order to keep pests from entering the containers in order to prevent spoilage of fruit.

One of ordinary skill in the art would have been motivated to separate the seeds/rind/pulp via mechanical separation including the use of a centrifuge decanter (centrifuge filtration) in order to clarify the juice for packaging. It was clear from Elliot that the use of these means to produce juice was well known and conventional in the art. Further, although Elliot did not specifically teach what mesh screen they used for the centrifugal filtration, it is clear that an 80 mesh (177 micron) filtration size which is very close to the claimed filtration pore size was well known to be used in the art. Clearly, Ashurst et al. taught that the use of a 500 micrometer screen was in conventional use for fruit juice at the time the invention was made, the use thereof producing a pulpy fruit juice. One of ordinary skill in the art would have been motivated to optimize the filter size as well as the pressure on the centrifuge (based in-part on the centrifugal force) in order to best clarify the juice without clogging the filter. Additionally, it is determined that the mesh size of the sieve used to filter the noni juice

Art Unit: 1655

would have been varied dependent upon the desired consistency/turbidity of the juice.

The mesh size used for filtering is clearly a result effective variable; as the mesh size increases, the turbidity (i.e., pulp and other solid material) decreases while the clarity of the juice increases. Thus, the choice of mesh size is considered an obvious choice considering that one of ordinary skill in the art would have been well-aware of the relationship between mesh size and juice clarity, and further since mesh sizes for use with juices as claimed were already known in the art and available for use. In this respect, it is deemed obvious whether the juice of the claims contains or does not contain pulp. The inclusion of pulp of juice is deemed a matter of design choice based upon the desired turbidity of the resulting manufactured juice. Juices are routinely made with and without pulp (a well-known fact which can be seen on any supermarket shelf). Thus, to include or exclude pulp from a manufactured juice product is not deemed inventive and thus, does not render the process of the claims patentable.

Solomon taught that the use of noni juice for treatment of various ailments was wide-spread (see, *Id.*). Solomon specifically prescribed a noni juice formulation comprising 89% noni juice and 11% of each of blueberry and grape juice with other added fruit juices. Therefore, people drank MC juice mixed with grape and blueberry juice. It is deemed that when people ingested this juice, scavenging lipid hydroperoxides would have been an inherent consequence, since the product of the claims which is administered is the same as the product of the prior art (noni juice

Art Unit: 1655

admixed with blueberry and grape juice) and the patient (consumer) population is the same.

Applicant is directed to MPEP § 2111.04:

The determination of whether each of these clauses is a limitation in a claim depends on the specific facts of the case. In *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005), the court held that when a “whereby” clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention.” *Id.* However, the court noted (quoting *Minton v. Nat’l Ass’n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)) that a ***“whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.”*** *Id.* (emphasis added).

Hence, it follows from *Minton v. Nat’l Ass’n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003) that claims which state that lipid peroxidation is inhibited via the administration of the noni juice do not hold much patentable weight because this inhibition is deemed to be an intended result of the process step. Note that claim 1 is not a method for inhibiting lipid peroxides, but rather a method for manufacturing and administering an MC juice product. Nevertheless, because people naturally possess lipid hydroperoxides, the act of drinking the juice as disclosed by Solomon, would have inherently manifested the results of inhibiting/preventing/reversing lipid peroxidation.

Art Unit: 1655

One of ordinary skill in the art would have been motivated to place or store MC fruit in plastic containers such as the ones disclosed by Beaven in order to either ripen the MC fruits or to transport the MC fruit to the fruit processing plant/facility. The ordinary artisan would have had a reasonable expectation of success in producing the claimed invention, in that the use of plastic containers were known for fruit/vegetable storage and for ripening.

It was clear that centrifuges which operated at about 150 psi were known in the art at the time the invention was made according to Astrauskas et al. Although Astrauskas et al. is not directed toward the separation of fruit juices, it is deemed that the ordinary artisan would draw upon the teachings in the prior art regarding centrifuges which were capable of separating the liquid and juice of solids as per the teachings of Elliot and would have had a reasonable expectation that a centrifuge operating at 150 psi would have successfully carried out separation of the liquid from the solid material. It is noted that $\text{psi} = \text{psig} + 14.695948804$ (atmospheric pressure). And therefore, the teachings of Astauskas et al. teaching 150 psi – 14.7 (approx) = 135.3 psig is within the psig as Instantly claimed.

Claim 26 which states 'wherein the consumption of said beverage composition produces dose-dependent effects' is deemed an intrinsic consequence of noni juice ingestion and is not a method step which would impart patentability to the method claims.

The instantly claimed method steps are deemed an obvious variation of the traditional method for producing noni juice. While the steps in the method are a more sophisticated, mechanical means for processing noni juice, the movement to conventional, modernized, juice processing techniques for obtaining MC juice is considered non-inventive. There is no one step in the claimed processing method which is a novel step. And although there is no one teaching which describes processing of noni in the steps required by the claimed invention, it is deemed that the ordinary artisan, having the above-cited references before him or her would have been motivated to arrive at the claimed invention by routine experimentation and optimization seeing that each claimed step in the manufacturing process are conventional steps in juice manufacture. While Applicants repeatedly argue that their method is rendered unobvious by the prior art teachings because the noni juice prepared by the instantly claimed method produces an unexpected result with regard to inhibiting lipid peroxidation; such arguments remain mere allegation absent any verifiable data to substantiate such a claim. There is no evidence of record which demonstrates that the method as Instantly claimed will produce an MC juice which is superior to known MC juices with regard to inhibition of lipid peroxidation. Thus, Applicants' arguments are not convincing and such arguments, lacking evidence in support thereof, are not persuasive to obviate this rejection.

Art Unit: 1655

1, 5-12 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirazumi (1998) in view of Solomon (1998) in view of Ashurst (1999) in view of Elliot (US 1,885,401) in view of Beaven (GB 2215173A) in view of Astrauskas et al. (US 3,953,582) in view of Weil (2000).

The teachings of Hirazumi, Solomon, Ashurst, Elliot, Beaven and Astrauskas et al. were discussed *supra*. None of these references specifically suggested the incorporation of an additional component for inhibiting lipid peroxidation as required by claims 24 and 25.

Weil (2000) reporting for the Northern Echo taught a product named 'Premium Noniplus' which comprised a combination of MC and aloe and elderberry. Weil reported that elderberry was rich in antioxidants (p. 2).

One of ordinary skill in the art would have been motivated to have combined MC juice with another antioxidant containing juice such as elderberry juice in order to have increased the total amount of ingested antioxidants in order to provide an additive antioxidant (inhibition of lipid peroxidation) effect.

The Supreme court has acknowledged that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person**

Art Unit: 1655

of ordinary skill can implement a predictable variation..103 likely bars its patentability...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...

...the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

It is noted that Applicants' arguments pertaining to the previous rejections are rendered moot considering that said rejections have been removed. Applicants' amendment to the claims necessitated a new search and consideration of the prior art due to the inclusion of a new specified number of days of ripening, and storing the fruit of the noni. Upon considering the Hirazumi and Solomon references, the Examiner chose to restructure the rejections to such an extent that the new rejections were not absolutely necessitated by Applicants' amendments to the claims; hence the reason this action is non-final.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

/Patricia Leith/

Application/Control Number: 09/997,588

Page 19

Art Unit: 1655

Primary Examiner, Art Unit 1655